OHSU
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Dockets Management Branch (HFA-305)
Food and Drug Administration
5360 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket Nº 97N-484S
Suitability Determination for Donors of
Human Cellular and Tissue-Based Products

To Whom it Concerns:

This letter is written in response to the proposed rules regarding egg donation published by the FDA in the Federal Register on September 30, 1999. As clinicians, our IVF team strongly objects to the proposal that egg donation be performed only with embryos that have been cryopreserved and quarantined with the egg donor being screened prior to the IVF cycle and six months after the donation. This objection is based on the fact that there is no evidence that oocytes, embryos or isolated sperm cells used with IVF-ET are vectors of the diseases listed in the FDA proposal. HIV or other infectious diseases have not been shown to be passed by IVF-ET in the 21-years in which IVF has been performed. Requiring that embryos be quarantined until they are considered to be "suitable for embryo transfer" will significantly increase patient cost and will also significantly decrease the success rate for this therapy. Further, there will be unnecessary death of embryos from the proposed rules to mandate freezing and a delay in childbirth in an already older patient who utilizes this therapy.

The FDA does not seem to understand that using semen carries with it a much different risk for transmission of disease than the hypothetical risk associated with the use of isolated and washed sperm cells, oocytes and embryos. It seems as though the FDA is interfering with the practice of medicine based on no scientific or medical merit.

Sincerely,

Marsha J. Gorrill, M.D.
Director, In Vitro Fertilization Program at the
Oregon Health Sciences University

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